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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,150	01/24/2005	Dan Peters	2815-0297PUS1	9211
2292 7590 10/03/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER O DELL, DAVID K	
			ART UNIT	PAPER NUMBER
			1625	
			NOTIFICATION DATE	DELIVERY MODE
			10/03/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

## Office Action Summary

Application No.

10/522,150

Applicant(s)

PETERS ET AL.

Examiner

David K. O'Dell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 37-65 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. This application is a 371 of PCT/DK03/00538 filed 08/13/2003 which claims priority to Danish application PA 2002-01208 filed 08/14/2002 and Danish application 2002 01472 filed 10/02/2002.
2. Claims 37-65 are pending.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

3. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 37-40, 44, 56 drawn to compounds and compositions reading on n is 2, X is O, A is benzimidazole drawn to azabicycl[2.2.2]octane-benzimidazole-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group II, Claims 37-40, 47, 48, 56 drawn to compounds and compositions reading on n is 2, X is O, -CH<sub>2</sub>-O, or -CH<sub>2</sub>-CH<sub>2</sub>-, A is isoindole-1,3-dione drawn to azabicycl[2.2.2]octane-isoindole-1,3-diones. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group III, Claims 37-40, 44, 45, 46, 56 drawn to compounds and compositions reading on n is 2, X is O, A is pyridazine drawn to azabicycl[2.2.2]octane-pyridazine-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group IV, Claims 37-43, 56 drawn to compounds and compositions reading on n is 2, X is O, A is phenyl, indenyl, naphthyl or tetrahydronaphthyl, drawn to azabicycl[2.2.2]octane-(phenyl/tetrahydronaphthyl/naphthyl/indenyl)-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

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Group V, Claims 37-40, 44, 45, 46, 56 drawn to compounds and compositions reading on n is 2, X is O, A is 1,2,4-thiadiazole, drawn to azabicycl[2.2.2]octane-1,2,4-thiadiazole-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VI, Claims 37-40, 44, 45, 46, 56 drawn to compounds and compositions reading on n is 2, X is O, A is thiazole, drawn to azabicycl[2.2.2]octane-thiazole-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VII, Claims 37-40, 44, 47, 48, 56 drawn to compounds and compositions reading on n is 2, X is O, A is quinoline, drawn to azabicycl[2.2.2]octane-quinoline-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VIII, Claims 37-40, 44, 47, 48, 56 drawn to compounds and compositions reading on n is 2, X is O, A is quinoxaline, drawn to azabicycl[2.2.2]octane-quinoxaline-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group IX, Claims 37-40, 47, 55, 56 drawn to compounds and compositions reading on n is 2, X is O, A is imidazo[1,2-b]pyridazine, drawn to azabicycl[2.2.2]octane-imidazo[1,2-b]pyridazine-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group X, Claims 37-40, 44, 47, 48, 56 drawn to compounds and compositions reading on n is 2, X is O, A is benzothiazole or benzoisothiazole, drawn to azabicycl[2.2.2]octane-(benzothiazole/benzoisothiazole)-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XI, Claims 37-40, 47, 48, 56 drawn to compounds and compositions reading on n is 2, X is O or -CH<sub>2</sub>-O-, A is benzotriazole, drawn to azabicycl[2.2.2]octane-benzotriazole-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XII, Claims 37-40, 44, 45, 46, 56 drawn to compounds and compositions reading on n is 2, X is O, A is thiophene, drawn to azabicycl[2.2.2]octane-thiophene-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XIII, Claims 37-40, 44, 47, 48, 56 drawn to compounds and compositions reading on n is 2, X is O, A is benzoxazole, drawn to azabicycl[2.2.2]octane-benzoxazole-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

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Group XIV, Claims 37-40, 47, 56 drawn to compounds and compositions reading on n is 2, X is O, A is dibenzofuran, drawn to azabicycl[2.2.2]octane-dibenzofuran-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XV, Claims 37-40, 44-45, 47, 49-54, 56 remaining compounds not delineated in any of the above groups drawn to for example compounds and compositions reading on n is 2, X is O, A is pyrrolo[1,2-b]pyridazine, drawn to azabicycl[2.2.2]octane-pyrrolo[1,2-b]pyridazine-ethers. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XVI, claims 57-59, drawn to methods of treating central nervous system disorders, limited in scope to one of the compounds of groups I-XV. If this group is elected, a single disclosed species of compound as well as a single disclosed species of central nervous system disorder, is also required. Further restriction based on the election will be made.

Group XVII, claims 57, 60 drawn to methods of treating diseases disorders etc. associated with "smooth muscle contractions", limited in scope to one of the compounds of groups I-XV. If this group is elected, a single disclosed species of compound as well as a single disclosed species of diseases disorders etc. associated with "smooth muscle contractions", is also required. Further restriction based on the election will be made.

Group XVIII, claims 57, 61 drawn to methods of treating disease disorder etc. is associated with the endocrine system, limited in scope to one of the compounds of groups I-XV. If this group is elected, a single disclosed species of compound as well as a single disclosed species of disease disorder etc. is associated with the endocrine system, is also required. Further restriction based on the election will be made.

Group XIX, claims 57, 62 drawn to methods of treating neurodegenerative disorders, limited in scope to one of the compounds of groups I-XV. If this group is elected, a single disclosed species of compound as well as a single disclosed species of neurodegenerative disorders, is also required. Further restriction based on the election will be made.

Group XX, claims 57, 63 drawn to methods of treating inflammatory disorders, limited in scope to one of the compounds of groups I-XV. If this group is elected, a single disclosed species of compound as well as a single disclosed species of inflammatory disorder, is also required. Further restriction based on the election will be made.

Group XXI, claims 57, 64 drawn to methods of treating pain, limited in scope to one of the compounds of groups I-XV. If this group is elected, a single disclosed species of compound as well as a single disclosed species of pain, is also required. Further restriction based on the election will be made.

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Group XXII, claims 57, 65 drawn to methods of treating diseases associated with withdrawal, limited in scope to one of the compounds of groups I-XV. If this group is elected, a single disclosed species of compound as well as a single disclosed species of disease associated with withdrawal, is also required. Further restriction based on the election will be made.

The inventions listed as Groups I-XXII do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because:

**PCT Rule 13.1** states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

**PCT Rule 13.2** states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, of if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B **Part 1(b)**, indicates that "special technical features" means those technical features that as a whole define a contribution over the prior art.

Annex B **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter e.g. product, process, use, apparatus, means, etc.

Annex B **Part 1(e)**, indicates that the permissible combinations of different categories of claims. **Part 1(e)I**, states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, **Part 1(f)**, indicates the "Markush practice" of alternatives in a single claim. **Part 1(f)I**, indicates the technical relationship and the same or corresponding special technical feature is considered to be met when (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B), Annex B, **Part 1(f)(i-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f) iv**, indicates that when all alternatives of a Markush grouping can be differently classified, it shall no, take alone, be considered justification for finding a lack of unity. **Part 1(f)v**, indicates that

"When dealing with alternatives, if it can be shown that at least *one* Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner"

In the instant case, at least one Markush alternative is not novel because prior art by U.S. Patent 5,646,289 recites the compounds of the instant case (cited in the international search

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report along with numerous other references) where many compounds such as thiadiazoles were produced where X is O, A is thiadiazole:

**Alternative synthesis of (±)-3-Chloro-4-(1-azabicyclo[2.2.2]octyl-3-oxy)-1,2,5-thiadiazole:**

0 A solution of 1-azabicyclo[2.2.2]octan-3-ol (1.2 g, 0.0092 mol) in THF (25 mL) was treated dropwise with 1.6M n-butyllithium in hexane (5.9 mL, 0.0095 mol). The solution was cooled to -8° C. and a solution of 3-chloro-4-ethylsulfonyl-1,2,5-thiadiazole (1.83 g, 0.0086 mol) in THF 5 (15 mL) was added dropwise. After 15 min, cooling was removed and the reaction stirred overnight. The reaction was treated with H<sub>2</sub>O (10 mL), diluted with ether (100 mL), and extracted with 1N HCl (25 mL). The aqueous solution was 0 washed with ether, made basic, and extracted with ether. The extracts were dried and the solvent evaporated to give crude (compound 12) (1.05 g) as a brownish liquid.

, thus the lack of a special technical feature is apparent.

Inventions I-XV and XVI-XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case at least the method of treating cardiovascular disease can be practiced with surgery.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to

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maintain dependency on the product claims or to otherwise include all the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's Primary examiner, Rita Desai can be reached on (571)272-0684. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

  
RITA DESAI  
PRIMARY EXAMINER 9/27/07